Preferred Drug List Committee Meeting

Meeting Minutes, Open Session

March 14, 2018 11:30 a.m.

DXC Technologies-Capital Room, 6511 SE Forbes Ave., Bldg. 283 J, Topeka, Kansas 66619

Board Members Present:

Taylor Gill, Pharm. D., BCPS, AAHIVP (Interim Chair)	Raymond Magee, M.D.	Megan Hedden, Pharm.D.
Emily Prohaska, Pharm.D., BCACP (Phone)	Wayne Wallace, M.D.	

Board Members Absent:

Donna Sweet, M.D., MACP (Chair)	Robert Haneke, Pharm.D.

KDHE-DHCF Staff:

Annette Grant, RPh (Phone)	Roxanne Chadwell, PharmD, CSP	Carol Arace, Sr. Admin. Asst.

HP Staff Present:

Ellen McCaffrey, RN, BSN	Kathy Kaesewurm, RN, BSN

HID Staff Present:

None

MCOs Present:

Jennifer Murff-United Healthcare	Angie Zhou-Sunflower	Lisa Todd-Amerigroup

Public Attendees:

Jim Baumann, Pfizer; Melissa Basil; Sandra Dirks; Angela Dugan; Rob Hansen, Pfizer; Laura Hill; Roy Lindfield; Anthony Locke, Tris Pharma; Julie McDavitt, Boethringer Ingelmeim; Michaela Skhylz, Sunflower; Jennifer Stoffel, Janssen; Hailey Sullivan

Item	Facilitator (s)	Notes
I. Call to Order	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	Dr. Gill called the March 14, 2018 PDL Committee meeting to order at 11:30am. Dr. Gill notified the attendees about public comment with the length of time to make a public comment being less than five minutes. She also requested that if anyone wishes to make a public comment, they must fill out and turn in to her the Conflict of Interest form prior to speaking.
I. Call to Order **A. Announcements**	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	Ms. Grant reminded everyone about the possible towing if anyone has parked south of the building. Dr. Gill asked Dr. Roxanne Chadwell to introduce herself as the new Assistant Pharmacy Program Manager with KDHE/DHCF.
II. Old Business **A. Review and Approval of December 13, 2017 Minutes**	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	The draft minutes from the December 13, 2017 meeting were reviewed. Request to amend to include the Appendix A document from the December 13, 2017 meeting. Dr. Magee moved to approve the minutes as amended. Dr. Wallace seconded the motion. The motion carried unanimously and the minutes were approved as amended.
II. Old Business **B. Consent Agenda Items** i. PDL New Drug Placements 1. Adzenys® ER Suspension 2. Protonix® Packets 3. Kenalog® 0.5% Ointment 4. Lyrica® solution 5. Keppra® solution 6. Seebri™ Neohaler® 7. Khedezla® 8. Luvox CR® 9. Prozac Weekly® 10. Apidra® 11. Apidra® Solostar® 12. Afrezza®	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	**Background:** At the September 13, 2017 PDL meeting the Committee agreed to the 'Consent Agenda Items' old business. 'Pre-approval for drug molecule dose form, dose device, IR/ER, and strength of a current PDL drug with the State providing 'Consent Agenda Items' with a list of agents, under 'Old Business' as a report to the Committee at each PDL meeting.' The list would be titled "Appendix A*". **Public Comment:** None **Committee Discussion:** Dr. Wallace moved to approve Appendix A. Dr. Magee seconded the motion. The motion carried unanimously. *Appendix A follows the minutes below.

Item	Facilitator (s)	Notes
13. Humalog® KwikPen® 14. Humalog® Junior KwikPen® 15. Bydureon® Bcise™		
III. New Business **A. ADHD- Amphetamine Type - Class Review- New Agent: (Mydayis®)** i. Public Comment ii. Committee Discussion/Recommendations	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	**Background:** The ADHD – Amphetamine Type class was first reviewed and approved by the PDL committee in March 2017. The FDA recently approved Mydayis®, which is being presented for approval today. Mydayis® is an extended-release, mixed salts amphetamine product indicated for the treatment of ADHD in patients 13 years of age or older. Included for the committee's review are the package inserts and a class comparison chart. **Public Comment:** None. **Committee Discussion:** Dr. Magee moved to approve. Dr. Hedden seconded the motion. The motion carried unanimously.
III. New Business **B. ADHD- Methylphenidate Type- Class Review- New Agent: (Cotempla XR-ODT™)** i. Public Comment ii. Committee Discussion/Recommendations	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	**Background:** The ADHD – Methylphenidate Type class was first reviewed and approved by the PDL committee in March 2017. The FDA recently approved Cotempla XR-ODT™, which is being presented for approval today. Cotempla XR-ODT™ is an extended-release orally disintegrating tablet indicated for the treatment of ADHD in pediatric patients 6-17 years of age. Included for the committee's review are the package inserts and a class comparison chart. **Public Comment:** None. **Committee Discussion:** Dr. Wallace moved to approve. Dr. Wallace seconded the motion.

Item	Facilitator (s)	Notes
		The motion carried unanimously.
III. New Business **C. ADHD - Miscellaneous Type - New Class- (Clonidine IR, Guanfacine IR, Strattera®, Kapvay®, Intuniv®)** i. Public Comment ii. Committee Discussion/Recommendations	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	**Background:** The ADHD – Miscellaneous Type class was first presented to the PDL committee in March 2017. The PDL committee approved the addition of the class with the following agents, Strattera®, Kapvay® and Intuniv®. The DUR Board tabled the addition of this class to the PDL at their April 2017 meeting and requested the addition of the immediate release agents, clonidine and guanfacine. The class is being presented for consideration today, with the addition of clonidine IR and guanfacine IR. Included for the committee's review are package inserts and a class comparison chart. **Public Comment:** None. **Committee Discussion:** Dr. Prohaska moved to approve. Dr. Magee seconded the motion. The motion carried unanimously.
III. New Business **D. Anticholinergic for Maintenance of COPD- Class Review- New Agent: (Lonhala™ Magnair™)** i. Public Comment ii. Committee Discussion/Recommendations	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	**Background:** The Anticholinergics for Maintenance of COPD class was last reviewed March 16, 2016 when Seebri™Neohaler® (glycopyrrolate) was reviewed and approved for inclusion in the class. Lonhala™Magnair™ (glycopyrrolate) is a long-acting muscarinic antagonist (LAMA) indicated for the long-term maintenance treatment of airflow obstruction in patients with COPD, including chronic bronchitis and/or emphysema. It gained FDA approval in December 2017 as the first nebulized LAMA approved for COPD in the U.S. Included for the committee's review are the package inserts and a class comparison chart. **Public Comment:** Sandra Dirks with Sunovion spoke on behalf of Lonhala™Magnair™. Julie McDavitt with Boethringer Ingelmeim spoke on behalf of Spiriva®. **Committee Discussion:** Dr. Prohaska moved to approve. Dr. Magee seconded the motion. The motion carried unanimously.

Item	Facilitator (s)	Notes
III. New Business **E. GLP-1 Receptor Agonists- Class Review- New Agent: (Ozempic®)** i. Public Comment ii. Committee Discussion/Recommendations	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	**Background:** This class was established at the March 2012 PDL meeting and was last reviewed March 2017 with the addition of Adlyxin (lixisenatide). Glucagon-Like Peptide-1 Receptor Agonists (GLP-1 RA) achieve glycemic control by mimicking the incretin hormone GLP-1. Their effects include increasing insulin secretion, decreasing glucagon release, increasing satiety and slowing gastric emptying. The newest addition proposed to this class is Ozempic® (semaglutide), a once weekly subcutaneous injection. Included for the committee's review are the package inserts and a class comparison chart. **Public Comment:** Jason Lurk with Novo Nordisk, spoke on behalf of Ozempic®. **Committee Discussion:** Dr. Magee moved to approve. Dr. Hedden seconded the motion. The motion carried unanimously.
III. New Business **F. Corticosteroids - Intermediate Potency Topical – Class Review -New Agents: Valisone® (All strengths and dose forms)** i. Public Comment ii. Committee Discussion/Recommendations	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	**Background:** Betamethasone valerate was reviewed and approved under this class at the September 13, 2017 meeting under the brand name Luxiq® (0.12% foam). It is being requested that Valisone® be reviewed and considered for inclusion on the PDL today. The addition of Valisone® would expand the approval of betamethasone valerate to include the 0.1% strength, which is available as a cream, lotion and ointment. Betamethasone valerate 0.1% is an intermediate potency topical corticosteroid. Included for the committee's review are the package inserts and a class comparison chart. **Public Comment:** None. **Committee Discussion:** Dr. Magee moved to approve. Dr. Hedden seconded the motion. The motion carried unanimously.

Item	Facilitator (s)	Notes
III. New Business **G. Corticosteroids -High Potency Topical – Class Review – New Agents: Lidex®, Lidex E®** i. Public Comment Committee ii. Discussion/Recommendations	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	**Background:** Fluocinonide was reviewed and approved under this class at the September 13, 2017 meeting under the brand name Vanos™ (0.1% cream). It is being requested that Lidex® and Lidex E® be reviewed and considered for inclusion on the PDL today. The addition of Lidex® and Lidex E® would expand the approval of fluocinonide to include the 0.05% strength, which is available as a cream (Lidex E®), gel, ointment, solution (Lidex®). Fluocinonide 0.05% is a high potency topical corticosteroid. Included for the committee's review are the package inserts and a class comparison chart. **Public Comment:** None. **Committee Discussion:** Dr. Magee moved to approve. Dr. Hedden seconded the motion. The motion carried unanimously.
III. New Business **H. Immunomodulation Agents- Psoriatic Arthritis- Class Review, New Agents: (Taltz®, Xeljanz®, Xeljanz XR®)** i. Public Comment ii. Committee Discussion/Recommendations	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	**Background:** The immunomodulation agent class for psoriatic arthritis was last reviewed by the PDL committee in December 2017, when Cimzia was presented and approved for inclusion to the class. This proposition requests for the addition of three additional agents newly indicated for the treatment of psoriatic arthritis. Taltz is an injectable humanized monoclonal antibody that selectively binds with interleukin-17A (IL-17A) cytokine. Inhibition of IL-17A inhibits the release of proinflammatory cytokines and chemokines. Typical side effects are those commonly seen in immunomodulating agents; including upper respiratory tract infection, infection, and antibody development. Xeljanz/Xeljanz XR is an oral targeted immune modulator that inhibits the intracellular tyrosine kinase called Janus kinase (JAK). Inhibition of JAK within the cell leads to a disruption in cellular signaling pathways, thereby disrupting the pathway that leads to inflammation. Common side effects include nasopharyngitis, upper respiratory tract infection, headache and diarrhea. Taltz, Xeljanz and Xeljanz XR were FDA approved for psoriatic arthritis. Included for the committee's review are the package inserts and a class comparison chart. **Public Comment:** Rob Hansen with Pfizer spoke on behalf of Xeljanz and Xeljanz XR.

Item	Facilitator (s)	Notes
		Committee Discussion: Dr. Magee moved to approve. Dr. Wallace seconded the motion. The motion carried unanimously.
III. New Business **I. Insulin – Short-Acting and Intermediate-Acting- Class Review- New Agents: (Fiasp®, Fiasp® Flextouch®)** i. Public Comment ii. Committee Discussion/Recommendations	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	**Background:** The short and intermediate acting insulin class was last reviewed by the PDL committee in May 2015, when Humalog® KwikPens®, Apidra®, Apidra Solostar® and Afrezza® were proposed and approved for inclusion to the class. Fiasp and Fiasp Flextouch is a formulation of insulin aspart, with two added excipients, niacinamide and L-Arginine. It is available as a multi-dose vial or pen-injector. When administered as a subcutaneous injection, Fiasp/Fiasp Flextouch is to be administered at the beginning of or within 20 minutes after starting a meal. Included for the committee's review are the package inserts and a class comparison chart. **Public Comment:** Jason Lurk with Novo Nordisk, spoke on behalf of Fiasp/Fiasp Flextouch. **Committee Discussion:** Dr. Magee moved to approve. Dr. Wallace seconded the motion. The motion carried unanimously.
III. New Business **J. Intranasal Agents – Corticosteroids – Class Review – New Agent: (Xhance™)** i. Public Comment ii. Committee Discussion/Recommendations	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	**Background:** This class was last reviewed in March 2013, with the addition of Qnasl®. In September 2017, the FDA approved Xhance™, an intranasal corticosteroid indicated for the treatment of nasal polyps in patients 18 years of age or older. Xhance™ utilizes an Optinose® Exhalation Delivery System (EDS) designed to enable drug delivery to areas of inflammation high and deep in the nasal passages. Included for the committee's review are the package inserts and a class comparison chart. **Public Comment:** None.

Item	Facilitator (s)	Notes
		Committee Discussion: Dr. Magee moved to approve. Dr. Wallace and Dr. Hedden seconded the motion. The motion carried unanimously.
III. New Business **K. Ophthalmic – Prostaglandin Analog- Class Review- New Agent: (Vyzulta™)** i. Public Comment ii. Committee Discussion/Recommendations	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	**Background:** This class was last reviewed in September 2014. Vyzulta™ (latanoprostene bunod) is indicated for the reduction of intraocular pressure (IOP) in patients with open-angle glaucoma or ocular hypertension. Vyzulta reduces IOP through a dual mechanism of action in which the medication is metabolized into two moieties; latanoprost acid and butanediol mononitrate. Included for the committee's review are package inserts and a class comparison chart. **Public Comment:** None. **Committee Discussion:** Dr. Magee moved to approve. Dr. Wallace seconded the motion. The motion carried unanimously.
III. New Business **L. Opioids -Short Acting – Class Review- New Agent: (Codeine)** i. Public Comment ii. Committee Discussion/Recommendations	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	**Background:** The Short-Acting Opioids class was last reviewed by the PDL committee as a new class in December 2017. This proposition requests the addition of single agent codeine sulfate. Opioids are medically indicated for the reduction of both acute and chronic pain. Opioids work primarily through binding to the opioid mu-receptors in the brain, spinal cord, and smooth muscle. Binding of the opioid mu-receptor results in analgesia, euphoria, miosis, reduced GI motility, and respiratory depression. Included for the committee's review are the package inserts and a class comparison chart. **Public Comment:** None.

Item	Facilitator (s)	Notes
		Committee Discussion: Dr. Wallace moved to approve. Dr. Magee seconded the motion. The motion carried unanimously.
III. New Business **M. Proton Pump Inhibitors- Class Review- New Agent: (Zegerid®)** i. Public Comment ii. Committee Discussion/Recommendations	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	**Background:** The Proton Pump Inhibitors Class was last brought to the PDL committee June 21, 2017, when Dexilant SoluTab (deslansoprazole) was proposed and approved for inclusion in the class. Zegerid (omeprazole/sodium bicarbonate) is indicated for the short-term treatment of duodenal ulcer, erosive esophagitis, gastric ulcer, the treatment of GERD and reduction of risk of upper GI bleeding in critically ill patients. Zegerid is available as a capsule and powder for oral suspension. Included for the committee's review are package inserts and a class comparison chart. **Public Comment:** None. **Committee Discussion:** Dr. Magee moved to approve. Dr. Wallace seconded the motion. The motion carried unanimously.
III. New Business **N. Class Name Change Request- Fluorouracil Agents to Actinic Keratosis Agents- New Agents: (Picato®, Solaraze® 3% Gel)** i. Public Comment ii. Committee Discussion/Recommendations	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	**Background:** The addition of the Fluorouracil Agents class and the agents within the class were presented to the PDL committee in September 2017 for approval. The medications in this class are indicated for the treatment of actinic keratosis. At the time of approval, only fluorouracil agents were requested to be added to the PDL. It is being requested today that two additional non-fluorouracil agents indicated for actinic keratosis be considered for addition to the PDL under a new class name of Actinic Keratosis Agents to encompass additional treatments for this indication. Picato® (ingenol mebutate) is a topical gel used for actinic keratosis. It is approved for short, 2 or 3 consecutive day, once-daily dosing in adult patients. Solaraze® (diclofenac) is a topical NSAID, in which the 3% gel is specifically indicated for the treatment of actinic keratosis.

Item	Facilitator (s)	Notes
		Solaraze is approved for use in adult patients and is applied twice daily for a duration of 60-90 days. Included for the committee's review are the package inserts and a class comparison chart. **Public Comment:** None. **Committee Discussion:** Dr. Magee moved to approve the name change and add the two agents as clinically equivalent. Dr. Wallace seconded the motion. The motion carried unanimously.
III. New Business **O. Request to separate DPP-4 Inhibitor combination agents and DPP-4 Inhibitor single agents into two separate classes.** i. Public Comment ii. Committee Discussion/Recommendations	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	**Background:** The DPP-4 Inhibitor class was last reviewed in June 2017 with the addition of Qtern® (dapagliflozin/saxagliptin). As it currently exists, this PDL class includes a variety of DPP-4 Inhibitor single agents and combination products. It is being requested today that the committee consider separating this class into two separate classes to better classify these agents. The two proposed classes are as follows: 1) DPP-4 Inhibitors 2) DPP-4 Inhibitor Combination Products. Included for the committee's review are the package inserts and the class comparison charts. – DPP-4 Inhibitors o Januvia, Onglyza, Nesina, Tradjenta – DPP-4 Inhibitor Combination Products o Janumet, Janumet XR, Kombiglyze XR, Jentadueto, Jentadueto XR, Kazano, Oseni **Public Comment:** Julie McDavitt with Boethringer Ingelmeim spoke on behalf of Tradjenta. **Committee Discussion:** Dr. Magee moved to approve. Dr. Wallace seconded the motion. The motion carried unanimously.

Item	Facilitator (s)	Notes
III. New Business **P. Request to separate SGLT2 Inhibitors into three separate classes –** o **- New Class - SGLT2 Inhibitors, New Agent: (Steglatro™)** o **- New Class - SGLT2 Inhibitor/DPP-4 Inhibitor, New Agent: (Steglujan™)** o **- New Class - SGLT2 Inhibitors/Biguanide Combination, New Agent: (Segluromet™)** i. Public Comment ii. Committee Discussion/Recommendations	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	**Background:** The SGLT2 Inhibitors class was last reviewed in September 2017 with the addition of Xigduo XR® (dapagliflozin/metformin ER). As it currently exists, this PDL class includes a variety of SGLT2 single agents and combination products. As more agents gain FDA approval, there are now multiple agents in each category. It is being requested today that the committee consider separating this class into three separate classes to better classify these agents. The three proposed classes are as follows: 1) SGLT2 Inhibitors 2) SGLT2 Inhibitor/DPP-4 Inhibitor 3) SGLT2 Inhibitor/Biguanide Combination Products. - New Class – SGLT2 Inhibitors, New Agents: (Steglatro™) This class of drugs is an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. There are currently three SGLT2 Inhibitor single agents on the PDL: Invokana, Farxiga and Jardiance. This proposition is requesting the addition of the newly approved agent, Steglatro™ (ertugliflozin). Steglatro™ is a once daily oral tablet. Included for the committee's review are the package inserts and a class comparison chart. - New Class – SGLT2 Inhibitor/DPP-4 Inhibitor, New Agents: (Steglujan™) This class of drugs is an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. There are currently two SGLT2 Inhibitor/DPP-4 Inhibitor combination products on the PDL: Glyxambi and Qtern. This proposition is requesting the addition of the newly approved agent, Steglujan™. Steglujan™ is a combination of the SGLT2 inhibitor, ertugliflozin, and the DPP-4 inhibitor, sitagliptin. It is a once daily oral tablet. Included for the committee's review are the package inserts and a class comparison chart. - New Class – SGLT2 Inhibitor/Biguanide Combination Products, New Agents: (Segluromet™) This class of drugs is an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes mellitus. There are currently five SGLT2 Inhibitor/Biguanide (metformin) combination products on the PDL: Invokamet, Invokamet XR, Synjardy, Synjardy XR and Xigduo XR. This proposition is requesting the addition of the newly approved agent, Segluromet™, which is a combination of ertugliflozin and metformin. This medication is an oral tablet that is dosed twice daily. Included for the committee's review are the package inserts and a class comparison chart. **Public Comment:** Julie McDavitt with Boethringer Ingelmeim spoke on behalf of Jardiance. Ralph Galten with Merck spoke on behalf of Steglatro™.

Item	Facilitator (s)	Notes
		Committee Discussion: Dr. Prohaska moved to approve splitting the class. Dr. Magee seconded the motion. The motion carried unanimously. Dr. Wallace moved to add the agents as clinically equivalent. Dr. Hedden seconded the motion. The motion carried unanimously.
IV. Open Public Comment	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	Jim Baumann with Pfizer requested the Committee pull agents off the Consent Agenda list and make it an agenda item when there is public comment for that particular agent. He also asked if there was anything that could be done with letting the public know of the changes in times for the meetings. Dr. Gill reminded the public that all of the PDL meetings with the exception of the September (considered annual meeting), will be 11:30am to 1pm. The September annual meeting will be at 10am.
V. Adjourn	*Taylor Gill, Pharm. D., BCPS, AAHIVP*	Dr. Gill adjourned the meeting at 12:39pm.

Appendix A March 2018 Consent Agenda Item List This PDL option/process was approved 09/13/2017 by the PDL Committee and 10/11/2017 by the DUR Board.				
Drug Proposed - Consent Agenda Item	**Compare Drug**	**Supporting information**	**Meeting Date listed on the PDL Agenda**	**PDL Committee Approval Yes/No**
Adzenys® ER Suspension	Adzenys XR-ODT™	Same reference drug, different dosage form	3/14/2018	Yes
Protonix® Packets	Protonix®	Same reference drug, different dosage form	3/14/2018	Yes
Kenalog® 0.5% Ointment	Kenalog® (cream, spray)	Same reference drug, different strength and dosage form	3/14/2018	Yes
Lyrica® solution	Lyrica®	Same reference drug, different dosage form	3/14/2018	Yes
Keppra® solution	Keppra®	Same reference drug, different dosage form	3/14/2018	Yes
Seebri™ Neohaler®	Seebri™ Neohaler®	Previously reviewed and approved by PDL 3/16/16	3/14/2018	Yes
Khedezla®	Desvenlafaxine	Previously PDL approved as all brands, generics, dose forms 3/8/2017	3/14/2018	Yes
Luvox CR®	Fluvoxamine	Previously PDL approved as all brands, generics, dose forms 3/8/2017	3/14/2018	Yes
Prozac Weekly®	Fluoxetine	Previously PDL approved as all brands, generics, dose forms 3/8/2017	3/14/2018	Yes
Apidra®	Apidra®	Previously reviewed and approved by PDL 3/13/2015	3/14/2018	Yes
Apidra® Solostar®	Apidra®	Previously reviewed and approved by PDL 3/13/2015	3/14/2018	Yes
Afrezza®	Afrezza®	Previously reviewed and approved by PDL 3/13/2015	3/14/2018	Yes
Humalog® KwikPen®	Humalog®	Previously reviewed and approved by PDL 3/13/2015	3/14/2018	Yes
Humalog® Junior KwikPen®	Humalog®	Same reference drug, different dosage form	3/14/2018	Yes
Bydureon® Bcise™	Bydureon®	Same reference drug, different dosage form	3/14/2018	Yes